WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Typographical errors in claims 1 and 3 have been corrected. The rejection of the previously pending claims under § 112, second paragraph cannot be maintained. The written description of the als1 protein in the vaccine of the present invention is clearly contained in the present specification. Moreover, the amended claims in the pending RCE eliminate any premise of a written description objection based on strain-to-strain variability in the ALS protein in *Candidas albicans*.

First, the written description objection is based on the supposition that strain-to-strain variability deprives claims to an ALS1 protein of an adequate written description based on the current specification. Support for the claimed invention is plainly found in recitation of the structure and portions of the ALS1 protein that permit use of the compound in the vaccine composition of the invention. Merely because a reference suggests variation in a portion of a polynucleotide sequence encoding a protein, this does not mean that a written description cannot exist for the translated polypeptide molecule. There is no basis in fact or rule of law requiring an individual recitation of the sequence of each species to describe a property that is shared by the members of the genus.

Applicants have, in full compliance with the statute and the new examination guidelines propagated at 66 Fed. Reg. No. 4, pp 1099-1111 (January 5, 2001), provided a written description of the invention as broadly as it is claimed. Please note that the guidelines are satisfied by providing "any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor has possession of the claimed invention." Id. at 1105. See also the comment at paragraph 16 and the readily distinguishable case of Tronzo v. Biomet, 156 F.3d 1154 (Fed. Cir. 1998). Here, the applicants describe the general and specific properties of the ALS1 polypeptide including the structure and function of the pertinent protein domains, the general and

context-specific function of the protein, the protein's role in the pathogenesis of C. albicans, and the efficacy of the ALS1 protein in terms of disruption of adherence of the organism in the pathogenic mechanism. Most importantly, the ALS1 protein was shown to be a surface protein, having an N-terminal signal peptide, a C-terminal GPI anchor, and a central tandem repeat region.

Second, even if the original objection to the written description were sustainable, the amended claim 1 specifies an N-terminal fragment of the ALS1 protein. Thus, the premise for the Section 112, second paragraph rejection is eliminated because no strain-to-strain variation is seen in this region of the polypeptide. The strain-to-strain variability cited by the Examiner only exists in the tandem repeat portion of the polynucleotide sequence – there is a very high level of conservation of sequences in the N-terminal region and in the N-terminal fragment of the protein after translation. If required, Applicants are prepared to submit data confirming this fact.

THE AMENDED CLAIMS ARE NOT ANTICIPATED BY THE HOYER ET AL. (J.Bacteriol. 1998) REFERENCE.

The amended claims specify that the pharmaceutical composition encompassed by the claims contains a carrier for injection or infusion – this is a structural limitation -- and that the composition produces an effective immune response – this limitation is also definite and certain because it defines a physical property characteristic of the vaccine composition. There is no meaningful disclosure in the Hoyer et al. reference of the formulation of an N-terminal als1 protein together with a carrier to yield an effective result as a vaccine, and no disclosure of a composition that meets these limitations as defined in claim 1.

THE CLAIMS, AS AMENDED, ARE NOT RENDERED UNPATENTABLE BY 35 U.S.C. § 103.

Applicants previously noted that Hoyer et al. does not disclose any useful immunological function for the als1 protein and does not reach the necessary conclusion from merely speculating that the als1 protein has a potential role in the adhesion function. Thus, the amended claims recite a composition that does not inherently possess the same function as the protein molecule disclosed by Hoyer et al. because Hoyer et al. do not disclose a vaccine formulation that includes a carrier or an N-terminal fragment, or which has been demonstrated to yield any immune response.

Applicants submit that the claims are in condition for allowance and request such action accordingly.

Respectfully submitted,

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Dated: September 22, 2003

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